

## Clinical Edit Criteria Proposal

Drug/Drug Class: **Botulinum Toxin Type A (Botox) Clinical Edit Therapy Edit**

Prepared for: Missouri Medicaid  
Prepared by: Heritage Information Systems, Inc.

☐ New Criteria

☒ Revision of Existing Criteria

### Executive Summary

**Purpose:** To control costs by following evidence based medical guidelines to ensure appropriate use of Botox Type A.

**Why was this Issue Selected:** Botulinum toxin type A has both cosmetic and non-cosmetic FDA-approved uses. Additionally, Botox averages close to \$1300.00 per prescription. This clinical edit is designed to assure prudent prescribing of this agent for non-cosmetic uses only.

Program-specific information:	Drug	Claims	Expense
	• Botulinum Injection	304	\$533,933

**Setting & Population:** All patients  $\geq$  18 years of age.

<b>Type of Criteria:</b>	<input type="checkbox"/> Increased risk of ADE	<input type="checkbox"/> Non-Preferred Agent
	<input checked="" type="checkbox"/> Appropriate Indications	<input type="checkbox"/>

<b>Data Sources:</b>	<input checked="" type="checkbox"/> Only administrative databases	<input type="checkbox"/> Databases + Prescriber-supplied
----------------------	---	--

## Purpose of Clinical Edit Criteria

Under the Omnibus Budget Reconciliation Act of 1993, Congress clinical edit is used to control utilization of products that have very narrow indications or high abuse potential. While prescription expenditures are increasing at double-digit rates, payors are also evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. Clinical edit criteria assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Clinical edit criteria can also reduce the risk for adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

## Setting & Population

- Drug class for review: Botulinum toxin type A (Botox<sup>®</sup>)
- Age range: Adult patients  $\geq 18$  years
- Gender: Male & female

## Approval Criteria

- Therapy will be approved for the following indications:

Approval Diagnoses				
Condition	Submitted ICD-9 Diagnoses	Inferred Drugs	History Date Range	Client Approval (Initials)
Blepharospasm	333.81	--	365 days	
Spasmodic torticollis	333.83	--	365 days	
Strabismus	378	--	365 days	
Cerebral Palsy	343	--	365 days	
Cervical Dystonia Torticollis, unspecified	723.5	--	365 days	
Spastic Hemiplegia	342.11	--	365 days	



## Denial Criteria

- Inappropriate Diagnosis

## Required Documentation

Laboratory results:

☐  
☐

MedWatch form:

Progress notes:

☐  
☐

Other:

## Disposition of Edit

- **Denial:** Exception 681 “Step Therapy”

## References

1. Allergen Pharmaceuticals Ireland. Botox prescribing information. Irvine, CA. July 2002. Accessed online June 9, 2003 at <http://www.botox.com/site/>.
2. Drug Facts and Comparisons, p. 1234-37, 2003.
3. Mayer, NH., Simpson DM. “Spasticity, Etiology, Evaluation, Management and the Role of Botulinum Toxin”, We Move. September 2002

